

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/012357

International filing date (day/month/year)
01.11.2004

Priority date (day/month/year)
03.11.2003

International Patent Classification (IPC) or both national classification and IPC
A61M15/00

Applicant
GLAXO GROUP LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2004/012357**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2004/012357**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial
applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 32, 33

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 32, 33

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2004/012357

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-31
	No: Claims	-
Inventive step (IS)	Yes: Claims	-
	No: Claims	1-31
Industrial applicability (IA)	Yes: Claims	1-31
	No: Claims	-

2. Citations and explanations**see separate sheet**

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/012357**Re Item III.**

Claims 32 and 33 were not searched in view of Article 17(2)(a)(ii) PCT and therefore no substantive examination can be performed. Furthermore, claims 32 and 33 do not specify any technical features which can be the subject of examination. Consequently, no opinion is formulated under Article 34(4)(a)(ii) PCT.

Re Item V.

- 1 The following documents are referred to in this communication:
D1 : WO 03/035151 A (GLAXO GROUP LIMITED; EDGERLEY, DAVID) 1 May 2003 (2003-05-01)
D2 : EP 0 928 618 A (INNOVATA BIOMED LIMITED) 14 July 1999 (1999-07-14)
D3 : WO 02/098495 A (INNOVATA BIOMED LIMITED; BRAITHWAITE, PHILIP) 12 December 2002 (2002-12-12)

- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not inventive in the sense of Article 33(3) PCT.
Document D1 discloses (see page 28, line 26 to page 35, line 2):

a hand-held device having as housing (200), a track in the housing, a chain of medicament containers (100) in the track and a conveying mechanism (206, 208, 210, 212) adapted to convey the chain along the track.

The subject-matter of claim 1 differs from this disclosure in that the medicament containers are specified to be capsules.

On page 26, line 20, document D1 mentions the use of capsules as an option, without specifying any details of that particular design. It is considered that if there is a difference between a peelable strip and a capsule, it lies strictly within the means to open the container, and not within the means for conveying. Therefore, it is considered that the subject-matter of claim 1 does not involve an inventive step (Article 33(3) PCT).

**WRITTEN OPINION OF THE
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International application No.

PCT/EP2004/012357

A similar objection can be made in view of documents D2 (see paragraphs 107 to 112) or D3 (see page 6, line 28 to page 7, line 12).

- 3 Dependent claims 2-31 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT). The reasons therefore are the following:

Dependent claims 2 to 20 and 29 to 31 appear to relate only to the drive of the conveying mechanism, which consist of sprockets and gear wheels. Document D1 discloses the basics of such a mechanism. The choice of using a plurality of these mechanisms does not involve an inventive step.

The features of the dependent claims relating to the chain of capsules (claims 21 to 28) do not clearly indicate a difference between the chain of capsules and the plurality of pockets disclosed in D1.

- 4 The device disclosed in claim 1 is industrial applicable and therefore the requirements of Article 33(4) PCT are met.

Claims 2 to 31 depend from claim 1 and refer to further embodiments of the device described in claim 1 and thus meet the requirements of Article 33(4) PCT for the same reasons explained above.